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10/585,863	02/07/2007	Guangxia Gao	Q95957	7734

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,863	GAO ET AL.	
	Examiner	Art Unit	
	YONG D. PAK	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-16* is/are pending in the application.

4a) Of the above claim(s) *5-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/11/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is 371 of PCT/CN04/00039.

The preliminary amendment filed May 30, 2009, amending claims 1-3, 5-7, 9-12, and 14-15, canceling claim 13, adding claim 16, and amending page 2 of the specification, has been entered.

Claims 1-12 and 14-16 are pending. Claims 5-12 are withdrawn. Claims 1-4 and 14-16 are under consideration.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on May 30, 2009 is acknowledged. The traversal is on the ground(s) that the special technical feature, variant of MLV-RT of SEQ ID NO:2 wherein the amino acid at position 84 is replaced with an amino acid with a side chain shorter than glutamine is not disclosed by Jin et al. This is not found persuasive because the special technical feature that links Groups I and II is now amended to encompass any variant of the MLV-RT of SEQ ID NO:2, wherein said variant comprises an amino acid with a side chain shorter than that of glutamine position 84 and comprises of any other amino acid at other amino acid positions. *** discloses such a variant. Therefore, the technical feature linking Groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 30, 2009.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 11, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to **(A)** a variant of the Moloney murine leukemia virus reverse transcriptase (MLV-RT) of SEQ ID NO:2, wherein the amino acid at position 84 is an amino acid with a side chain shorter than that of Gln, such as Ala, Ser, Asp, or

Asn, **(B)** a variant of the wild type MLV-RT of SEQ ID NO:9, wherein said variant has an amino acid mutation at position 84 such that the glutamine is replaced with an amino acid with an amino acid with a side chain shorter than that of Gln, **(C)** said variant of (A) wherein Asn at position 524 of SEQ ID NO:2 is replaced with Asp, wherein the function of the variant of (A), (B) , and (C) is not recited.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, for claim 16, the limitation "has an amino acid mutation at position 84" provides no description on the structure of other parts of the variant because the claimed variant is not limited to only the mutation at position 84 of SEQ ID NO:9. Similarly, for claims 1-4 and 14-15, the claims are not limited to only the mutation at position 84 and/or 524. Therefore, while the variant comprises the recited mutations, the same variant comprises any amino acids in any other positions, wherein said variant has no function, unknown function, and any function. Thus, Examiner has interpreted the claims broadly to encompass variants of SEQ ID NO:2 or 9, wherein the variant comprises a mutation at position 84 and/or 524 and one or more amino acid mutations at any other amino acid positions. Therefore, the claims encompass polypeptides having unknown structure and unknown function.

In *University of California v. Eli Lilly & Co.,* 43 USPQZd 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, (or) chemical name,' of the claimed subject

matter sufficient to distinguish it from other materials". As indicated in MPEP 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The claims are drawn to polypeptides having unknown structure and unknown function. The specification only describes two specific ML-VRT variants of single ML-VRT having the amino acid sequence of SEQ ID NO:9, wherein the variant laccase consists of substitutions at positions 84 with an Ala residue and/or at position 524 with an Asn residue and the variant has ML-VRT activity. While MPEP 2163 acknowledges that in certain situations "one species adequately supports a genus," it also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." In view of the widely variant species encompassed by the genus, two variants of the ML-VRT of SEQ ID NO:9 are not enough and does not

constitute a representative number of species to describe the whole genus of any or all variants of SEQ ID NO:2 or 9and there is no evidence on the record of the above mentioned two mutants of SEQ ID NO:9 and the structure of any or all variants of SEQ ID NO:2 or 9. Therefore, the specification fails to describe a representative species of the genus comprising any or all variants having any structure.

The claims are also drawn to many functionally unrelated polypeptides encompassed within the scope of these clams, including partial sequences, resulting in a substantial variation within the genus. The genus of these polypeptides comprise a large variable genus with the potentiality of having different activity or no activity. The specification only describes two specific ML-VRT variants of single ML-VRT having the amino acid sequence of SEQ ID NO:9, wherein the variant laccase consists of substitutions at positions 84 with an Ala residue and/or at position 524 with an Asn residue and the variant has ML-VRT activity. While MPEP 2163 acknowledges that in certain situations "one species adequately supports a genus," it also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." In view of the widely variant species encompassed by the genus, this one example is not enough and does not constitute a representative number of species to describe the whole genus of any or all variants, recombinant and mutants of SEQ ID NO:2 or 9 and having unknown activity, and there is no evidence on the record of the relationship between the structure of the above two variants and the structure of any or all recombinant, variant and mutant of SEQ ID NO:2 or 9 and having or unknown

activity. The specification also fails to describe additional representative species of the polypeptides by any identifying characteristics or properties of the polypeptides, for which no predictability of function is apparent. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 1-4 and 14-16.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-4 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for two specific ML-VRT variants of single ML-VRT having the amino acid sequence of SEQ ID NO:9, wherein the variant laccase consists of substitutions at positions 84 with an Ala residue and/or at position 524 with an Asn residue and the variant has ML-VRT activity, does not reasonably provide enablement for polypeptides having unknown structure and unknown function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to **(A)** a variant of the Moloney murine leukemia virus reverse transcriptase (MLV-RT) of SEQ ID NO:2, wherein the amino acid at position 84 is an amino acid with a side chain shorter than that of Gln, such as Ala, Ser, Asp, or Asn, **(B)** a variant of the wild type MLV-RT of SEQ ID NO:9, wherein said variant has an amino acid mutation at position 84 such that the glutamine is replaced with an amino acid with an amino acid with a side chain shorter than that of Gln, **(C)** said variant of (A) wherein Asn at position 524 of SEQ ID NO:2 is replaced with Asp, wherein the function of the variant of (A), (B) , and (C) is not recited.

The breadth of the claims.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, for claim 16, the limitation "has an amino acid mutation at position 84" provides no description on the structure of other parts of the variant because the claimed variant is not limited to only the mutation at position 84 of SEQ ID NO:9. Similarly, for claims 1-4 and 14-15, the claims are not limited to only the mutation at position 84 and/or 524. Therefore, while

the variant comprises the recited mutations, the same variant comprises any amino acids in any other positions, wherein said variant has no function, unknown function, and any function. Thus, Examiner has interpreted the claims broadly to encompass variants of SEQ ID NO:2 or 9, wherein the variant comprises a mutation at position 84 and/or 524 and one or more amino acid mutations at any other amino acid positions. Therefore, the claims encompass polypeptides having unknown structure and unknown function.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides of virtually any structure and unknown function. In the instant case, the specification only enables two specific ML-VRT variants of single ML-VRT having the amino acid sequence of SEQ ID NO:9, wherein the variant laccase consists of substitutions at positions 84 with an Ala residue and/or at position 524 with an Asn residue and the variant has ML-VRT activity.

The quantity of experimentation required to practice the claimed invention based on the teachings of the specification.

While enzyme isolation techniques, recombinant and mutagenesis techniques were known in the art at the time of the invention, e.g. mutagenesis, and it is routine in the art to screen for variants comprising multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art

would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

In the absence of: (a) rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function, (b) a correlation between structure and function of ML-VRT activity, the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. One of skill in the art would have to test these infinite possible polypeptides to determine (1) which mutants have ML-VRT activity, (2) the specific substrates targeted by such proteins and (3) how to use those polypeptides not have ML-VRT activity. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, as is the case herein, the specification must provide a reasonable amount of guidance which respect to the direction in which the experimentation should proceed so that a reasonable number of species can be selected for testing. In view of the fact that such guidance has not been provided in the instant specification, it would require undue experimentation to enable the full scope of the claims

The state of prior art, the relative skill of those in the art, and predictability or unpredictability of the art.

Since the amino acid sequence of the mutant determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant

of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. In the instant case, neither the specification or the art provide a correlation between structure and activity such that one of skill in the art can envision the structure of any polypeptides having the same biological function as that of the polypeptide of SEQ ID NO:2 or 9 or predict the function of a polypeptide from its primary structure. In addition, the art does not provide any teaching or guidance as to (1) which amino acids within the polypeptides of SEQ ID NO:2 or 9 (other than the amino acid at positions 84 and 524) can be modified and which ones are conserved such that one of skill in the art can make the recited polypeptides having the same biological activity as that of the polypeptide of SEQ ID NO:2, (2) which segments of the polypeptide of SEQ ID NO:2 or 9 are essential for activity, and (3) the general tolerance of ML-VRT to structural modifications and the extent of such tolerance. The art clearly teaches that changes in a protein's amino acid sequence to obtain the desired activity without any guidance/knowledge as to which amino acids in a protein are required for that activity is highly unpredictable. At the time of the invention there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity. For example, Branden et al. (introduction to Protein Structure, Garland Publishing Inc., New York, page 247, 1991 – form PTO-892) teach that (1) protein engineers are frequently surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes, (2) the often surprising results obtained by experiments

where single mutations are made reveal how little is known about the rules of protein stability, and (3) the difficulties in designing de novo stable proteins with specific functions.

In addition, since the claims encompass polypeptides having any function, one of skill in the art can not envision the function of these polypeptides from the structure of SEQ ID NO:2 or 9. Further, the function of a polypeptide cannot be predicted from its structure and the specification does not teach how to use polypeptides having any function or having no activity. The quantity of experimentation in this area is extremely large since there is significant variability in the activity of the polynucleotides in the claims. It would require significant study to identify the actual function of the encoded polypeptides and identifying a use for the encoded polypeptide would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its activity. Even very similar proteins may have every different functions. In the current case, where no specific information is known regarding the function, it is entirely unpredictable what function and activity will be found for the protein.

The amount of direction or guidance presented and the existence of working examples.

The specification only enables two specific ML-VRT variants of single ML-VRT having the amino acid sequence of SEQ ID NO:9, wherein the variant laccase consists of substitutions at positions 84 with an Ala residue and/or at position 524 with an Asn residue and the variant has ML-VRT activity. However, the speciation fails to provide any information as to (1) specific substrates associated with the ML-VRT of SEQ ID NO:2 or 9, (2) structural elements required in a polypeptide having ML-VRT activity, or (3) which are the structural elements in the polypeptide of SEQ ID NO:2 or 9 that are essential to display ML-VRT activity. No correlation between structure and function of having laccase activity has been presented. There is no information or guidance as to which amino acid residues in the polypeptides of SEQ ID NO:2 or 9 can be modified and which ones are to be conserved to create a polypeptide displaying the same activity as that of the polypeptides of SEQ ID NO:2 or 9.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability of the prior art in regard to structural changes and their effect on function and the lack of knowledge about a correlation between structure and function, an undue experimentation would be necessary one having ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having the desired biological characteristics recited in the claims are unpredictable and the experimentation left to those skilled in the art is

unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Germann et al. (Proc. Natl. Acad. Sci (1986) 83: 8854-8858 – cited previously on form PTO-892).

Claims 1-2 and 16 are drawn to **(A)** a variant of the Moloney murine leukemia virus reverse transcriptase (MLV-RT) of SEQ ID NO:2, wherein the amino acid at position 84 is an amino acid with a side chain shorter than that of Gln, **(B)** a variant of the wild type MLV-RT of SEQ ID NO:9, wherein said variant has an amino acid mutation at position 84 such that the glutamine is replaced with an amino acid with an amino acid with a side chain shorter than that of Gln, **(C)** said variant of (A) wherein Asn at position 524 of SEQ ID NO:2 is replaced with Asp, wherein the function of the variant of (A), (B) , and (C) is not recited.

It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, for claim 16, the limitation "has an amino acid mutation at position 84" provides no description on the structure of other parts of the variant because the claimed variant is not limited to only

the mutation at position 84 of SEQ ID NO:9. Similarly, for claims 1-2, the claims are not limited to only the mutation at position 84 and/or 524. Therefore, while the variant comprises the recited mutations, the same variant comprises any amino acids in any other positions, wherein said variant has no function, unknown function, and any function. Thus, Examiner has interpreted the claims broadly to encompass (1) any variants of SEQ ID NO:2 or 9, wherein the variant comprises an amino acid with a side chain shorter than that of glutamine at a position corresponding to position 84 of SEQ ID NO:2 and one or more amino acid mutations at any other amino acid positions (claims 1, 3-4 and 16) and (2) any variants of SEQ ID NO:2 or 9, wherein the variant comprises an amino acid with a side chain shorter than that of glutamine at position corresponding to 84 of SEQ ID NO:2, Asp residue at a position corresponding to position 524, and one or more amino acid mutations at any other amino acid positions (claims 2), wherein said variants of (1) and (2) have any function.

Kato et al. (Jpn. J. Genet. 62, 127-137, 1987 –form PTO-892) discloses a reverse transcriptase (Figure. 1-2 on page 131). The polypeptide of Kato et al. has an amino acid with a side chain shorter than that of glutamine at a position corresponding to position 84 of SEQ ID NO:2 or 9, Asp residue at a position corresponding to position 524 of SEQ ID NO:2 or 9 and one or more amino acid mutations at any other amino acid positions (Figure 1-2 on page 131 and see attached sequence alignment). Since (1) there is no limitation on the structure of the claimed variant except having an Asp residue at position corresponding to position 524 of SEQ ID NO:2 or 9 and an amino acid with a side chain shorter than that of glutamine at a position corresponding to

position 84 of SEQ ID NO:2 or 9 and (2) the instant claims are drawn to a product, which may be produced by the recited modification/starting material or not, Examiner takes the position that the polypeptide of kato et al. reads on the instant claims. Therefore, whether the claimed product is obtained from the ML-VRT of SEQ ID NO:2 or 9 or obtained from any source (including wild type proteins), as long as the resulting product has the structural limitations recited in the claims, the product is still the same and is within the scope of the claimed invention. Therefore, the reference of kato et al. anticipates claims 1-2 and 16.

Conclusion

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/
Primary Examiner, Art Unit 1652